Remarks

Claims 17, 19-23 and 25-37 are pending in this application. Claims 17, 19-23 and 25-37 have been amended in various particulars as indicated hereinabove.

Claims 29-34 were rejected under 35 U.S.C. 112, second paragraph. Applicant believes that Claim 29-34 as amended are now in compliance with the requirements of 35 U.S.C. 112, second paragraph. In particular, Applicant draws the attention of the Patent Office to the following.

The Patent Office objected to the notation of the centesimal homeopathic dilutions C12, C30 in the Claims. The present amended claims continue to refer to the same centesimal homeopathic dilutions (C12, C30), because these terms are well known and accepted in the relevant art. Applicant asserts that homeopathic dilutions and homeopathic technology have been known in the field of homeopathy in the US to anyone of average skill in that field for almost 200 years, as explained in the NIH report enclosed with this response.

Page 1 of the specification as originally filed describes the homeopathic potentiation technology of producing homeopathic dilutions (decimal dilutions and centesimal dilutions, as well as simultaneous shaking). Additionally, enclosed with this response is a PDF file is a copy of the English language translation of the German Homeopathic Pharmacopoeia (1978, British Homeopathic Association, 5th Supplement of 1991), which has an extensive description of the potentization/potentiation method and various types of homeopathic dilutions. Applicant asserts that the referenced homeopathic dilution terms are fundamental and basic in the field of homeopathy, definite and well known to any person of average skill in the art of homeopathy[1].

[1] Please refer to the same terminology and usage in **US Patent 5, 629,286** "*Homeopathic dilutions of growth factors*"; **US Patent 5,834,443** "*Composition and method for treating herpes simplex*"; **US Patent 7,229,648** "*Homeopathic formulations useful for treating pain and/or inflammation*"; **US Patent 6,485,480** "*Treatment methods using homeopathic preparations of growth factors*".

Therefore, rejection of these definite homeopathic terms is inappropriate in view of the requirements of 35 U.S.C. 112, second paragraph, and should be withdrawn. (MPEP 706.03(d))

Claims 17, 19-23 and 25-37 were rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) Jonsson *et al.* (US Patent No. 4,292,324). This rejection is respectfully traversed for the following reasons.

In particular, the Patent Office has stated that the active substance and the homeopathically diluted potentiated substance are the same substance in different concentrations. In response to that, Applicant asserts as follows.

It is well established that a claim is anticipated under 35 U.S.C. §102, only if each and every element of the claim is found in a single prior art reference.[2] Moreover, to anticipate a claim under 35 U.S.C. §102, a single source must contain each and every element of the claim "arranged as in the claim."[3, 4] Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.[5] If each and every element of a claim is not found in a single reference, there can be no anticipation.

For an obviousness rejection to be proper, the Patent Office must meet the burden of establishing a prima facie case of obviousness. The Patent Office must meet the burden of establishing that all elements of the invention are disclosed in the cited publications, which must have a suggestion, teaching or motivation for one of ordinary skill in the art to modify a reference or combined references.[6] The cited publications

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[2] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).
[3] *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).
[4] *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q. 2d 1766, 1768 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).
[5] *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).
[6] In re Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).

should explicitly provide a reasonable expectation of success, determined from the position of one of ordinary skill in the art at the time the invention was made.[7]

Applicant respectfully brings to the attention of the Patent Office the fact that the term "potentiated" was introduced in the amended Claims to more specifically claim the present invention. Specification of the original application as filed discloses on page 2 that term. The term "potentiated" is a well-defined term in the field of homeopathy.

Furthermore, the Patent Office is asked to refer to the report on "Q&A about Homeopathy", issued by the National Center for Complementary and Alternative Medicine of the National Institute of Health (NIH) (copy enclosed). On page 2 of the enclosed copy, the NIH report explains (emphasis added):

"In the late 1700s, Samuel Hahnemann, a physician, chemist, and linguist in Germany, proposed a new approach to treating illness."

"Hahnemann added two additional elements to homeopathy:

- A concept that became "potentization" which holds that systematically diluting a substance, with vigorous shaking at each step of dilution, makes the remedy more, not less, effective by extracting the vital essence of the substance. If dilution continues to a point where the substance's molecules are gone, homeopathy holds that the "memory" of them--that is, the effects they exerted on the surrounding water molecules--may still be therapeutic.

- A concept that treatment should be selected based upon a total picture of an individual and his symptoms, not solely upon symptoms of a disease. Homeopaths evaluate not only a person's physical symptoms but her emotions, mental states, lifestyle, nutrition, and other aspects. In homeopathy, different people with the same symptoms may receive different homeopathic remedies.

Hans Burch Gram, a Boston-born doctor, studied homeopathy in Europe and introduced it into the United States in 1825. European immigrants trained in homeopathy also made the treatment increasingly available in America. In 1835, the first homeopathic medical college was established in Allentown, Pennsylvania. By the turn of the 20th century, 8 percent of all American medical practitioners were homeopaths, and there were 20 homeopathic medical colleges and more than 100 homeopathic hospitals in the United States. "

As follows from the above, the concept of potentization as extreme dilution, as well as preparing a remedy by extremely diluting the substance in a series of steps, has been known and well defined in the US since at least the first half of the 19th century.

[7] In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); Amgen v. Chugai Pharmaceuticals Co., 18 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Homeopathy asserts that this process can maintain a substance's healing properties regardless of how many times it has been diluted. Many homeopathic remedies are so highly diluted that not one molecule of the original substance remains in the homeopathic dilution. Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified the properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. While no definite scientific theory exists to explain how potentiated homeopathic remedies work, it has been shown that they work.[8] It has also been known that the term "potentiated" defines such homeopathic remedies. It is not the same substance or preparation as a simply diluted substance of the same chemical substance with the same molecules present in the solvent or carrier. Please refer to the Rule 132 Declaration of inventor Oleg I. Epshtein providing additional experimental data on the efficacy of the claimed medication, clinical trials and the research behind those data.

The potentiated form of a substance prepared in accordance with the homeopathic technology is a preparation different from just some non-potentiated preparation containing a chemically homogeneous substance. As explained in the specification and as in supported by the data on clinical trials presented in the Rule 132 Declaration of inventor Oleg I. Epshtein, claim element "potentiated medicinal preparation produced by the homeopathic technology" in independent Claim 17, or claim element "potentiated medicinal preparation produced by the homeopathic method" in independent Claim 23 and Claim 35 are fundamentally not the same as non-homeopathically diluted substances.

Therefore, Applicant asserts that no disclosure of the homeopathically potentiated medicinal preparation can be found anywhere in Jonsson. That patent had no disclosure of the homeopathic dilutions (homeopathic doses) of the potentiated preparations of any substance, regardless of its chemical composition, prepared by homeopathic technology. The degrees of dilution in Jonsson are non-homeopathic (not decimal or centesimal

[8] There are at least as many as 25 schools and colleges of homeopathy in the US alone. Please see the enclosed list of the US homeopathy schools.

dilutions), so no teaching or suggestion or motivation to use homeopathic dilutions of potentiated medicinal preparations could be found in that patent.

Therefore, Claim17 and its dependent Claims 19-22 in the present application comply with the requirements of 35 U.S.C. 102(b) or 103(a) and are patentable over the cited patent. For the same reasons, Claim 23 and its dependent Claims 25-28, Claim 35 and its dependent Claims 36-37 comply with the requirements of 35 U.S.C. 102(b) or 103(a) and are patentable over the cited patent.

Claim 29 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Cohen *et al.* (US Patent No. 3,901,967). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the C30 potency of the potentiated medicinal preparation of atropine sulfate, claimed in Claim 29, could be found in anywhere in the Cohen patent. Therefore, Claim 29 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

Claim 30 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Sirany (US Patent No. 4,987,127). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the C30 potency of the potentiated medicinal preparation of acetylsalicylic acid, claimed in Claim 30, could be found in anywhere in the Sirany patent. Therefore, Claim 30 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

Claim 31 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Nobile (US Patent No. 3,134,718). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the C12 potency of the potentiated medicinal preparation of prednizolon, claimed in Claim 31, could be found in

anywhere in the Nobile patent. Therefore, Claim 31 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

Claim 32 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Massey *et al.* (US Patent No. 4,839,341). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the C30 potency of the potentiated medicinal preparation of insulin, claimed in Claim 32, could be found in anywhere in the Massey patent. Therefore, Claim 32 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

Claim 33 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Jonsson *et al.* (US Patent No. 4,292,324). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the potentiated medicinal preparation of zinc paste, claimed in Claim 33, could be found in anywhere in the Jonsson patent. Therefore, Claim 33 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

Claim 34 was rejected under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) over Albert Stock John *et al.* (US Patent No. 3,032,584). This rejection is respectfully traversed for the same reasons as presented above.

Applicant respectfully asserts that no disclosure of the C200 potency of the potentiated medicinal preparation of sarcolysine, claimed in Claim 34, could be found in anywhere in the Albert Stock John patent. Therefore, Claim 34 is in compliance with the requirements of 35 U.S.C. 102(b) or 103(a) and is patentable over the cited patent.

On pages 6-7 of the Final Office Action of February 14, 2007, the Patent Office remarked that "it is not understood how two compounds having identical chemical formula can be totally different substances, have different properties and act in totally

different ways. Further, applicant has not provided any data showing that the combination produces a highly efficient medication with completely new properties that has never been known before."

In response to these statements, Applicant submits with this response the Rule 132 Declaration of inventor Oleg I. Epshtein, which provides data on the research behind the bipathy phenomenon, the data on the *in vivo* and *in vitro* experiments and the data on clinical trials devoted to studying the bipathic medications. The data presented in the Rule 132 Declaration of inventor Oleg I. Epshtein clearly show the efficacy of the combined bipathic medication comprised of a substance in a therapeutic dose and a potentiated homeopathic preparation made of a homeopathic dilution, as compared to the traditional non-bipathic remedies. Some of the results of the research and data described in the Rule 132 Declaration were published as the following references:

1. Aleksandrova NV, Gofman AG, Krylov EN, Epstein OI. Use of potentiated preparations to relieve alcohol and opium withdrawal syndromes// Bull Exp Biol Med. 2003;135 Suppl 1:163-6
2. Amosova EN, Zueva EP, Razina TG, Krylova SG, Shilova NV, Epstein OI. Potentiated cyclophosphane: experimental study of the effect on tumor development and efficiency of cytostatic therapy// Bull Exp Biol Med. 2003;135 Suppl 1:107-10.
3. Berchenko OG, Vorob'eva TM, Geiko VV. Morphine and its potentiated form: effects on pain sensitivity in rats // Bull Exp Biol Med. 2003;135 Suppl 1:105-6.
4. Vorob'eva TM, Berchenko OG, Geiko VV, Kolyadko SP, Bevzyuk DA, Pan IR, Epstein OI. Effect of potentiated antibodies to morphine on behavioral reactions in rats with morphine dependence //Bull Exp Biol Med. 2003;135 Suppl 1:34-5.
5. Zilov VG, Sudakov KV, Epstein OI. Elements of. Informational Biology and Medicine/ Monograph.M.:MGUL, 2000.-248 p.
6. Myagkova MA, Abramenko TV, Panchenko ON, Epstein OI. Antibodies to delta sleep-inducing Peptide in ultralow doses: study of the effect by enzyme immunoassay // Bull Exp Biol Med. 2003;135 Suppl 1:102-4

7. Petrov SI, Epstein OI. Effect of Potentiated Solutions on Mercury(II) Signal in Inversion Voltammetry // Bull Exp Biol Med. 2003;135 Suppl 1:99-101
8. Titkova AM, Epstein OI. Effect of Preparations from Potentiated Ethanol on the Content of Biogenic Monoamines and Metabolism of Ethanol in Tissues of Rats during Alcoholization // Bull Exp Biol Med. 2003;135 Suppl 1:36-8
9. Epstein OI. Regulatory activity of ultralow doses // Bull Exp Biol Med. 2003;135 Suppl 1:8-13
10. Epshtein OI, Beregovoi NA, Pankova TM, Sorokina NS, Starostina MV, Shtark MB. In Vitro Effects of Bipathic Treatment with Antibodies in Ultralow Doses during Long-Term Post-tetanic Potentiation // Bull Exp Biol Med. 2003;135 Suppl 1:111-3
11. Epstein OI, Vorob'eva M, Geiko VV, Berchenko OG. Psychoactive compounds and their antibodies: effect on self-stimulation of the lateral hypothalamus in morphinizedrats//
Bull Exp Biol Med. 2003;135 Suppl 1:132-3
12. Epstein OI, Voronina TA, Molodavkin GM, Belopolskaya MV, Kheyfets IA , Dugina YL, Sergeeva SA. The study of bipathy phenomenon of phenazepam// Bull Exp Biol. – 2007

With regard to the statement of the Patent Office that it is not understood how two compounds of the same chemical formula can be different, Applicant reminds the Patent Office that the potentiated medicinal preparation is such a highly diluted substance that its properties are not determined by the chemical substance, which, most likely, is not even present in the extremely diluted preparations, or is present in some minute amounts.

As explained above, many homeopathic remedies known to be effective are so highly diluted that not one molecule of the original substance remains in the homeopathic dilution. A potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified the properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. Homeopathically diluted

remedies have been around for about 200 years and have been shown to be effective. It has not been understood exactly how the bipathic phenomenon of the present invention works, but the exact scientific theory behind an observed phenomenon is not required to be explained or even known for the purposes of patentability of the presented Claims.[9] Nor do Applicant wishes to be tied to a specific scientific theory purporting to explain the claimed bipathic phenomenon.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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[9] ""[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg* , 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); see also *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests."). Furthermore, statements that a physiological phenomenon was observed are not inherently suspect simply because the underlying basis for the observation cannot be predicted or explained." *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464 (Fed. Cir. 1999).